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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,595	06/07/2002	Albrecht E. Sippel	WEICKM 14	5887
23599 7590 04/10/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER GAMETT, DANIEL C	
			ART UNIT	PAPER NUMBER
			1647	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No:

09/869,595

Applicant(s)

SIPPEL ET AL.

Examiner

Daniel C. Gamett, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 10-13, 15-19, 22-37, 40-47, 49-53, 55-71, 74-81, 83 and 84 is/are pending in the application.

4a) Of the above claim(s) 11-13, 29, 38, 44-47, 49-53, 55-60, 64-66, 71 and 74-78 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 10, 15-19, 22-28, 30-37, 40-43, 61-63, 67-70, 79-81, 83, and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendments of 12/21/2006 have been entered in full. Claims 3-9, 14, 20, 21, 39, 48, 54, 72, 73, and 82 are cancelled. Claims 11-13, 29, 38, 44-47, 49-53, 55-60, 64-66, 71, and 74-78 are withdrawn from consideration as being drawn to a non-elected invention. It is noted that the status identifier of amended claim 29 was incomplete and should have indicated the withdrawn status of the claim. Though the amendment is technically non-compliant, claim 29 is considered withdrawn and the amended claims are examined in the interest of advancing prosecution.
2. Claims 1, 2, 10, 15-19, 22-28, 30-37, 40-43, 61-63, 67-70, 79-81, 83, and 84 are under examination.
3. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
4. Upon further consideration, the previous indication of allowability of claims is hereby withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 112

6. Rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. The claim has not been amended and Applicant's response filed 12/21/2006 did not address the rejection of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claim 1,2, 10, 15-19, 22-28, 30-37, 40-43, 61, 63, 67-70, 79-81, 83, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression “naturally occurring”, in claim 1, is unclear because the term “naturally occurring” does not delineate the metes and bounds of the recited component. Although Ras proteins that are able to activate a signal pathway are known in the art, one cannot tell where a sequence came from by looking at it. A given functional Ras protein might be naturally occurring or derived by site-directed mutagenesis; it could even be both, as a sequence might be engineered in the lab and then found to occur naturally at some point in the future. It is noted that the instant specification does not provide an unambiguous definition for the term. The remaining claims are unclear as they depend from claim 1. It is suggested that “naturally occurring” seems to be unnecessary and could be simply omitted from the claim.
8. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a eukaryotic cell as claimed in claim 23, comprising at least one fusion protein with a third domain which is able to activate the signal pathway connected to a Ras protein in the eukaryotic cell, which is inactive or inactivatable in the absence of the eukaryotic fusion protein. The cell of claim 23 already comprises a fusion protein with a third

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domain which is able to activate the signal pathway connected to a Ras protein in the eukaryotic cell (see claim 19). Thus, either this claim is intended to recite the particular embodiment of the claimed cell wherein there is binding of ligand to the second domain or this claim may simply fails to further limit the previous claim with respect to the fusion protein. The expression, "which is inactive or inactivatable in the absence of the eukaryotic fusion protein" is also unclear. It may be another way of indicating "the intrinsic signal pathway connected to a Ras protein is inactivated in the eukaryotic cell", in which case it fails to further limit claim 23. If another meaning is intended, it should be noted that claims 19 and 23 do not provide antecedent basis for absence of the eukaryotic fusion protein.

9. Claims 62 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression, "cells in which at least under certain conditions a signal pathway connected to a Ras protein cannot be activated" in claims 62 and 63, is not merely broad, but is indefinite as it fails to apprise the skilled artisan of the metes and bounds of what is being claimed. Furthermore, the expression "where appropriate", which appears twice in each of claims 62 and 63, is unclear because neither the claims nor the specification provides a definition that delineates whether the recited components may be either appropriate or inappropriate for inclusion in a kit. In light of the specification, it is suggested that "optionally" would convey Applicant's intent without implying a value judgment.

10. Claim 62 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. The description of the third domain retains "able to activate the inactive or inactivatable signal pathway connected to a Ras protein in the cells when there is lack of binding...to the second domain." This mode of action is outside of the scope of enablement established in the rejection of this claim in the office action mailed 02/07/2006. The specification does not teach the skilled artisan how to make a fusion protein with this mode of action. The specification teaches only a fusion protein wherein the activity of the third domain is positively regulated by ligand binding to the second domain.

Conclusion

11. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Applicant's attention is directed to MPEP § 502.03, regarding the use of Internet e-mail. Subsection V states in part that, "Internet e-mail shall **NOT** be used to conduct an exchange of communications similar to those exchanged during telephone or personal interviews unless a written authorization has been given under Patent Internet Usage Policy Article 5 to use Internet e-mail. In such cases, a paper copy of the Internet e-mail contents **MUST** be made and placed in the patent application file...in the same manner as an Examiner Interview Summary Form is entered."

DCG

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3 April 2007



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SUPERVISORY PATENT EXAMINER
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